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510 (k) Summary of Safety and Effectiveness for BrainLAB hip unlimited and Ci hip unlimited

Manufacturer:

Address: BrainLAB AG
Kapellenstrasse 12
85622 Feldkirchen
Germany
Phone: +49 89 99 15 68 0
Fax: +49 89 99 15 68 33

Contact Person: Mr. Per Persson

Summary Date: November 18th, 2008

Device Name:

Trade name: BrainLAB hip unlimited, Ci hip unlimited

Common/Classification Name: BrainLAB Image Guided Surgery System / Instrument, Stereotaxic

Predicate Devices:
VectorVision® hip (K040368)
Navigation Software hip 3.1 on Ci (K052213)
VectorVision® hip V3.1, Biomet integration (K060468)
VectorVision® hip 4.0 (K 060727)
VectorVision® hip V3.1, DePuy integration (K072716)

Device Classification Name: Instrument, Stereotaxic
Regulatory Class: Class II

Intended Use:

BrainLAB hip unlimited is intended to be an intraoperative image-guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space either on a patient's preoperative image data being processed by a VectorVision or a Ci™ workstation or on an individual 3D-model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface.
The system is indicated for any medical condition in which the use of stereotactic surgery may be considered to be safe and effective and where a reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT, X-ray, MR based model of the anatomy. The system aids the surgeon to accurately navigate a hip endoprothesis to the preoperatively or intraoperatively planned position.

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Example orthopedic surgical procedures include but are not limited to:

Total Joint Replacement (TJR)
Revision surgery of TJR
Minimally Invasive Orthopedic Surgery
Tumor resection and bone/joint reconstruction

Device Description:

BrainLAB hip unlimited is intended to enable operational planning and navigation in orthopedic total hip replacement surgery. It links a surgical instrument, tracked by flexible passive markers to virtual computer image space on an individual 3D-model of the patient's bone, which is either generated through acquiring multiple landmarks on the bone surface or on patient's intra-operative acquired fluoroscopic images. **BrainLAB hip unlimited** uses the registered landmarks to navigate the needed surgical tools like cup reamer, cup inserter, stem broach handles and the implant, to the planned position.

BrainLAB hip unlimited allows 3-dimensional reconstruction of the relevant anatomical axes and planes of the pelvis and femur and alignment of the implants. The **BrainLAB hip unlimited** software has been designed to read in data of implants and tools if provided by the implant manufacturer and offers to individually choose the prosthesis during each surgery. If no implant data is available it is possible to provide information in order to achieve a generally targeted alignment relative to the bone orientation as defined by the operating surgeon. The **BrainLAB hip unlimited** software registers the patient data needed for planning and navigating the surgery intra-operatively without CT-based imaging. The system can be used to generally align tool orientations according to the anatomy described and defined by the landmarks acquired by the surgeon.

Technical Comparisons to the Predicate Device:

- The comparisons showed that the subject device is substantially equivalent to the predicate devices, as listed above. The fundamental scientific technology is unchanged. The modifications consist in improvements of the user-system interface, additional registration methods for pelvis and femur, a minimal-invasive way to measure leg length and offset, and the removal of CT-based functionality. The software was correspondingly modified to handle the added capabilities. A detailed list of changes can be found in the document "Experiences from previous products" in Appendix I of the hip unlimited pre-market notification.

Substantial equivalence:

BrainLAB hip unlimited has been verified and validated according to BrainLAB's procedures for product design and development. The validation proves the safety and effectiveness of the system. The information provided by BrainLAB in this 510 (k) application was found to be substantially equivalent with the predicate devices:

- **VectorVision® hip V3.1, DePuy integration** (K072716)
- **VectorVision® hip 4.0** (K 060727)
- **VectorVision® hip V3.1, Biomet integration** (K060468)
- **Navigation Software hip 3.1 on Ci** (K052213)
- **VectorVision® hip** (K 040368)

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Excluded features:

The following features are not part of the subject device and the accompanying documentation should be excluded:

- **Stem first / ROM-based THR registration**
- **Acquisition of labrum points in TAL registration**
- **Hip total and hemi-resurfacing procedures**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2009

BrainLAB AG
% Mr. Per Persson
Kapellenstrasse 12
85622 Feldkirchen
Germany

Re: K083483
Trade/Device Name: BrainLAB hip unlimited, Ci hip unlimited
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: OJO
Dated: March 16, 2009
Received: March 16, 2009

Dear Mr. Persson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K083483

Indications for Use

510(k) Number (if known): Not applicable

Device Name: BrainLAB hip unlimited

Indications For Use:

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Example orthopedic surgical procedures include but are not limited to:

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Revision surgery of TJR
Minimally Invasive Orthopedic Surgery
Tumor resection and bone/joint reconstruction

Nicholas Ogden for mkm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083483

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)